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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/522,253 | 01/30/2006 | Manuela Villa | 17766 (PC27648A) | 8815 |
| 7590 | | 06/14/2007 | | |
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| | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/522,253 | Applicant(s) VILLA ET AL. | |
| | Examiner Shawquia Young | Art Unit 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-12, 18, 19, 22 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-17, 20, 21 and 23-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>3/7/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-29 are currently pending in the instant application.

I. *Priority*

The instant application is a 371 of PCT/EP03/07851, filed on July 16, 2003 and claims benefit of US Provisional Application 60/398,120, filed on July 25, 2002.

II. *Information Disclosure Statement*

The information disclosure statement (IDS) submitted on March 7, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

III. *Restriction/Election*

A. Election: Applicant's Response

Applicants' election with traverse of Group IX in the reply filed on May 8, 2007 is acknowledged. The traversal is on the ground(s) that: (1) that the Restriction Requirement is not in compliance with 35 USC 121 and 37 CFR 1.141 and 1.142.

All of the Applicants' arguments have been considered but have not been found persuasive. It is pointed out that the restriction requirement is made under 35 U.S.C. 121 and 372. 35 U.S.C. 121 gives the Commissioner (Director) the authority to restrict applications to several claimed inventions when those inventions are found to be independent and distinct. The Examiner has indicated that more than one independent and distinct invention is claimed in this application and has restricted the claimed subject matter accordingly.

Applicants argue that the Restriction Requirement is not in compliance with 35 USC 121 and 37 CFR 1.141 and 1.142. Applicants further argue that the Office Action has not shown that the claimed subject matter in the various groups is independent and distinct. However, the instant application is a 371 application and therefore follows PCT rules. PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same corresponding special technical features. *"Special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.*

The Examiner wants to point out that the Applicants' special technical feature is within the core structure of formula I. The special technical feature has to remain constant among all of the compounds claimed in the invention. Therefore the special technical feature does not include variables. Applicants' special technical feature is the pyrazole group in the formula I. That is the only part of the structure that remains constant. As mentioned in the Office Action on page 8, the special technical feature does not define a contribution over the prior art (See, WO 02/12242 A2, for example). The above reference is not used for a prior art rejection but used to show applicants that their special technical feature is present in the prior art and therefore does not define a contribution over the prior art. Also, the core structure of formula I falls into two different classes. Pyrrolo-pyrazole compounds fall into class 548 whereas Pyrazolo-azepine

compounds fall into class 540.

The Restriction Requirement detailed the reasons for restriction between the groups. Different search considerations are involved (i.e., class/subclass searches, databases searches, etc.) for each of the groups listed. The inventions are classified into classes 514, 540, 546 and 548. However, each Class 514, 540, 546 and 548 encompasses numerous patents and published applications. For instance, Class 514 contained 165,171 patents and published applications. Therefore it would constitute a burden on the Examiner and the Patent Office's resources to examine the instant application in its entirety.

The Examiner also wants to mention that the groups discussed in the Restriction Requirement are distinct and independent because prior art that reads on the subject matter of one of the groups would not necessarily read on the subject matter of the other groups. Further, Applicants have mentioned in the claims that the compounds are a part of two different classes of compounds such as Pyrrolo-pyrazole and Pyrazolo-azepine which means that these are distinct and independent classes of compounds.

Applicants further suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. The Examiner wants to point out that the Examiner does not in any way contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Also, the Examiner understands about the

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continued increase of official fees and the potential limitation of an applicant's financial resources. However, there are various inventions within the instant application.

According to the PCT rules 13.1 and 13.2, the various inventions should follow the unity of invention requirement and the applicants' claims do not. The Examiner is only given a certain amount of time to examine an application and therefore because of the vastness of the subject matter claimed in the various inventions in the instant application, a restriction requirement has to be imposed. The restriction requirement is **MADE FINAL**.

Subject matter not encompassed by elected Group IX are withdrawn from further consideration pursuant to 37 CFR 1.142 (b), as being drawn to nonelected inventions.

IV. Rejections

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-17, 20 and 23-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The "derivatives" of the compounds of Claims 13-17, 20 and 23-28 are not defined in the specification so as to know the structures of the compounds that are included and/or excluded by the term. Therefore, the specification lacks adequate support for Claims 13-17, 20 and 23-28.

Claims 20, 21 and 23 are rejected under 35 U.S.C. 112, first paragraph, because

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the specification, while being enabling for a solid support selected from the group consisting of isocyanate polystyrenic resin, 2-chloro-trityl chloride resin, trityl chloride resin, p-nitrophenyl carbonate Wang resin and the bromo-4-methoxyphenylmethyl polystyrene does not reasonably provide enablement for any solid support. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case

The nature of the invention

The nature of the invention is a compound of formula (III), wherein Q is a solid support.

The state of the prior art

It is the state of the prior art that the term "solid support" found in the claims is defined as an insoluble, functionalized, polymeric material to which library members or reagents may be attached allowing them to be readily separated from excess reagents, soluble reaction by-products or solvents

(<<http://www.iupac.org/reports/1999/7112maclean/s.html>>).

There are available various types of resin used as solid supports. Some examples are Boc-amino acid-CMS resins, PL-HMBA resins, PL-oxime resins and Fmoc-amino acid-Rink resins (<<http://www.polymerlabs.com/products/000026.html>>).

The amount of direction or guidance present and the presence or absence of working examples

There is little direction or guidance present in the specification or working examples present in the specification are that defines or relates to what solid supports are being included in the elected invention. The term "solid support" is discussed on page 17 of the specification and reads on the following "Solid support-more preferably a residue derived from a resin selected from the group consisting of isocyanate polystyrenic resin, 2--chloro-trityl chloride resin, trityl chloride resin, p-nitrophenyl carbonate Wang resin and the bromo.-4-methoxyphenyl)methyl polystyrene." The only example given of a solid support are the resins mentioned above.

The breadth of the claims

The breadth of the claims is a compound of formula (III), wherein Q is a solid

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support.

The quantity of experimentation needed and the level of the skill in the art

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed is undue experimentation. One of skill in the art would need to prepare compounds with all types of solid support available without any direction as to what type of solid support is needed.

The level of skill in the art is high without showing or guidance as to how to make of a compound of formula (III) with a solid support attached it would require undue experimentation to figure out the starting materials, solvents, temperatures and reaction times that would provide the above compounds with a solid support attached.

To overcome this objection, Applicant should submit an amendment limiting the term "solid support" to what is supported by the disclosure.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-17, 20 and 23-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13-17, 20 and 23-28 are indefinite for the reasons set forth above under 35 U.S.C. 112, first paragraph. Claims 13-17, 20 and 23-28 are drawn to "a pyrrolo-pyrazole or pyrazolo-azepine

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derivative represented by formula (I).” However, the “derivative” of the compounds of Claims 13-17, 20 and 23-28 are not defined in the claims so as to know the metes and bounds of the claims. Therefore, the claims are indefinite.

Claims 24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically the phrase “as per coding system of tables I-III” renders the claims indefinite, as the tables I-III are not defined in the instant claim. The examiner must refer back to the instant specification to find the definition of tables I-III. A claim referring to the specification is improper except in rare instances and fails to particularly point out the subject matter that applicant regards as the invention.

Ex parte Fressola, 27 USPQ 2d 1608 (1993).

V. Objections

Claim Objection-Non Elected Subject Matter

Claims 13-17, 20 and 23-28 are objected to as containing non-elected subject matter. To overcome this objection, Applicant should submit an amendment deleting the non-elected subject matter.

VI. Conclusion

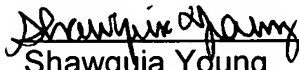
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-

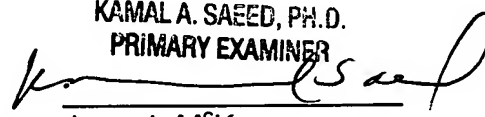
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272-9043. The examiner can normally be reached on 6:00 AM-2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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